

C. REMARKS

The claims have been amended in order to put the application in better form. Claim 1 has been amended in order to correct an error in wording, and Claim 7 has been amended in order to provide an antecedent basis for the subject matter claimed therein.

Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Salunke, et al. This rejection is respectfully traversed.

Claim 1 defines a method of producing purified papillomavirus virus-like particles. The method comprises (i) purifying disassembled papillomavirus virus-like particles (VLPs), and (ii) reassembling the disassembled papillomavirus virus-like particles (VLPs) from step (i) to produce purified papillomavirus virus-like particles.

The Examiner appears to have taken the position that because Salunke teaches the purification of a disassembled virus, that Salunke anticipates Claim 1.

The Examiner's rejection is misguided entirely. Salunke is directed entirely to the expression of polyomavirus capsomeres and polyomavirus capsid-like assemblies, and to the disassociation of polyoma virions to the capsomere level.

Claim 1, however, is directed to a process for producing purified papillomavirus virus-like particles, not polyoma virus as disclosed in Salunke. No mention whatsoever is made in Salunke that one can produce purified papillomavirus virus-like particles. In addition, it is clear from reading the specification that polyomaviruses are not papillomaviruses. The specification, from Page 7, line 14 to Page 8, line 4, discusses factors and conditions affecting the assembly of other viruses, such as polyomaviruses, as follows:

With respect thereto, it is generally known that VLP assembly can be affected by numerous factors. For example, factors and conditions known to affect assembly for other viruses include, by way of example: pH, ionic strength, post-translational modifications of viral capsid proteins, disulfide bonds, and divalent cation bonding, among others. For example, the importance of cation bonding, specifically calcium, in maintaining virion integrity has been shown for polyomavirus (Brady et al, *J. Virol.*, 23:717-724 (1977)), and rotavirus (Gajardo et al, *J. Virol.*, 71:2211-2216 (1997)). Also, disulfide bonds appear to be significant for stabilizing polyomavirus (Walter et al, *Cold Spring Har. Symp. Quant. Biol.*, 39:255-257 (1975); Brady et al, *J. Virol.*, 23:717-724 (1977); and SV40 viruses (Christansen et al, *J. Virol.*, 21:1079-1084 (1977)). Also, it is known that factors such as pH and ionic strength influence polyomavirus capsid stability,

presumably by affecting electrostatic interactions (Brady et al, *J. Virol.*, 23:717-724 (1977); Salunke et al, *Cell*, 46:895-904 (1986); Salunke et al, *Biophys. J.*, 56:887-900 (1980)). (emphasis added)

Thus, it is clear that Salunke, which is referred to in the above passage, does not disclose the present invention because Salunke is directed to polyomavirus, not papillomavirus.

The Examiner attempts to justify the rejection by stating that because Claim 1 is drafted broadly, it includes all conditions for purifying disassembled virus-like particles, and for reassembling disassembled virus-like particles, and that the purification step is taught by the cited prior art.

The Examiner has failed to recognize that, in order to anticipate, a reference must disclose all elements of a claim. (See Mehl/Biophile International Corp. v. Milgraum, 52 U.S.P.Q.2d 1303 (C.A.F.C. 1999), at 1306; Oney v. Ratliff, 51 U.S.P.Q.2d 1697 (C.A.F.C. 1999); Finnigan Corp. v. U.S. International Trade Commission, 51 U.S.P.Q.2d 1001 (C.A.F.C. 1999), at 1009; General Electric Co. v. Nintendo Co., Ltd., 50 U.S.P.Q.2d 1910 (C.A.F.C. 1999), at 1915.) Salunke is directed only to polyomavirus, and does not disclose the purification of papillomavirus virus-like particles. Also, the Examiner, in the Final Rejection, only mentions that Salunke teaches purification of disassembled polyomavirus. Nowhere in the rejection does the Examiner state that Salunke discloses the purification of papillomavirus virus-like particles, and the Examiner could not have done so because Salunke does not disclose the purification of papillomavirus virus-like particles. Salunke is directed instead to a different virus, i.e., polyomavirus. Therefore, Salunke does not disclose all of the elements of Claim 1, and therefore Salunke does not anticipate Claim 1. Salunke also does not even remotely suggest to one of ordinary skill in the art Applicants' process for producing purified papillomavirus virus-like particles as defined in Claim 1. Therefore, Salunke does not anticipate Claim 1, nor does Salunke render Claim 1 obvious to one of ordinary skill in the art. It is therefore respectfully requested that the rejection under 35 U.S.C. 102 (b) be reconsidered and withdrawn.

Claim 1 stands rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between steps. This rejection is respectfully traversed.

The Examiner appears to be taking the position that because Applicants did not invent VLP purification *per se*, that Applicants must narrow the protection of their claimed invention to detailed steps for purifying disassembled VLPs and/or for reassembling the disassembled VLPs.

The Examiner also appears to be taking the position that Applicants' invention in effect is directed only to optimized conditions for reassembling papillomavirus VLPs.

Assuming, solely for the sake of argument, that Applicants did not invent VLP purification *per se*, Applicants and only Applicants are the first to invent a process for producing purified papillomavirus virus-like particles by purifying disassembled papillomavirus virus-like particles, and reassembling the disassembled papillomavirus virus-like particles to produce purified papillomavirus virus-like particles. One skilled in the art would understand readily what is meant by purifying disassembled papillomavirus virus-like particles to produce purified papillomavirus virus-like particles. In addition, contrary to the Examiner's assertions, there is no gap between the step of purifying disassembled VLPs and the step of reassembling the disassembled VLPs.

Because Applicants are the first to invent a process for producing purified papillomavirus VLPs by purifying disassembled papillomavirus VLPs and then reassembling the disassembled VLPs, it would be contrary to the interests of justice to require Applicants to limit the scope of their protection to specific methods of reassembly of the disassembled virus-like particles and/or to specific methods to purifying disassembled papillomavirus virus-like particles, and enable one to avoid infringement by employing a process for producing purified papillomavirus VLPs which is outside the scope of Applicants' claims yet within the broad scope of Applicants' inventive discovery.

The Examiner notes that Applicants have optimized reassembly conditions for the reassembly of papillomavirus virus-like particles, and have obtained patents on parent applications claiming methods employing such conditions. The mere fact that Applicants have obtained such patents does not mean that Applicants cannot obtain a patent on a method for producing purified papillomavirus virus-like particles which includes a step of reassembling disassembled virus-like particles. As noted in Applicant's previous response filed on March 8, 2006, in addition to effecting reassembly of disassembled papillomavirus virus-like particles, the present invention also is directed to the purification of such virus-like particles, as is indicated in the specification of Page 9, paragraph 6; Page 12, lines 10-12; Page 22, lines 21-23; and Page 55, lines 16-22. Therefore, contrary to the Examiner's position, Applicants' invention, in addition to relating to the reassembly of disassembled papillomavirus virus-like particles, also relates to a process for producing purified virus-like particles which incorporates a reassembly step.

Therefore, for the above reasons and others, Claim 1 does not omit any essential steps and therefore is patentable under 35 U.S.C.112, second paragraph. It is therefore respectfully requested that the rejection under 35 U.S.C.112, second paragraph, be reconsidered and withdrawn.

For the above reasons and others, this application is in condition for allowance, and it is therefore respectfully requested that the rejections be reconsidered and withdrawn and a favorable action is hereby solicited.

Respectfully submitted,



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